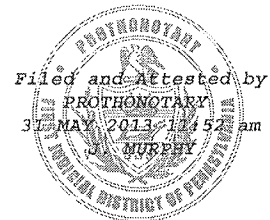


EXHIBIT A

KLINE & SPECTER, P.C.

By: Thomas R. Kline, Esquire/28895
By: Lee B. Balefsky, Esquire/25321
By: Michelle L. Tiger, Esquire/43872
1525 Locust Street
Philadelphia, PA 19102
(215) 772-1000

Attorneys for Plaintiff
Patricia L. Hammons



PATRICIA L. HAMMONS
705 South Meridian
Washington IN 47501
PLAINTIFF

v.

ETHICON, INC.,
Individually and/or d/b/a,
ETHICON WOMEN'S HEALTH
AND UROLOGY, a Division of
ETHICON, INC.

One Johnson & Johnson Plaza
New Brunswick NJ 08893
and

GYNECARE

One Johnson & Johnson Plaza
New Brunswick NJ 08893
and

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick NJ 08893
and

SECANT MEDICAL, INC.,
SECANT MEDICAL, LLC,
Individually and/or d/b/a and/or as a
Division of PRODESCO, INC.,
Collectively and/or Individually d/b/a
SECANT MEDICAL
700 Park Avenue
Perkasie PA 18944,

DEFENDANTS.

**PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION - CIVIL**

JURY TRIAL DEMANDED

**ASSESSMENT OF DAMAGES
HEARING IS REQUIRED**

**COMPLAINT AND JURY DEMAND
NEGLIGENCE AND PRODUCTS LIABILITY**

Plaintiff, Patricia L. Hammons, by and through her attorneys, Lee B. Balefsky, Esquire and Michelle L. Tiger, Esquire of Kline & Specter, P.C., files this Complaint against Ethicon, Inc., Ethicon Women's Health And Urology, A Division Of Ethicon, Inc., Gynecare, Johnson & Johnson, Secant Medical, Inc., Secant Medical, LLC, Secant Medical and Prodesco, Inc., both jointly and severally, the companies that designed, manufactured and/or marketed the medical devices inserted in Plaintiff Patricia L. Hammons. Accordingly, Plaintiff alleges as follows:

I. PARTIES

1. Plaintiff, Patricia L. Hammons, is an adult citizen and resident of the State of Indiana, residing at 705 South Meridian, Washington Indiana 45701.

2. Defendant, Johnson & Johnson, is a corporation, and according to its website, the world's largest and most diverse medical devices and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

3. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson, located in Somerville, New Jersey.

4. Defendant, Ethicon Women's Health and Urology, is a division of Ethicon, Inc., located in Somerville, New Jersey.

5. Defendant, Gynecare, is a division of Ethicon, Inc., located in Somerville, New Jersey (collectively, Defendants Ethicon, Inc., Ethicon Women's Health and Urology of Ethicon, Inc., Gynecare and Johnson & Johnson are referred to as the, "J&J Defendants").

6. Defendant Secant Medical, Inc. is a corporation located in Perkasi, Pennsylvania, which at all times material to this matter did business under the fictitious name, Secant Medical and/or as a division, subsidiary, agent, representative of, and/or successor in

interest to, and/or jointly with Defendants Prudesco, Inc., Secant Medical, LLC and/or Secant Medical.

7. Defendant Secant Medical, LLC. is a corporation located in Perkasie, Pennsylvania, which at all times material to this matter did business under the fictitious name, Secant Medical and/or as a division, subsidiary, agent, representative of, and/or successor in interest to, and/or jointly with Defendants Prudesco, Inc., Secant Medical, Inc, and/or Secant Medical.

8. Defendant Prodesco, Inc. is a corporation located in Perkasie, Pennsylvania, which at all times material to this matter did business under the fictitious name, Secant Medical and/or as a division, subsidiary, agent, representative of, and/or successor in interest to, and/or jointly with Defendants Secant Medical, Inc. and/or Secant Medical, LLC.

9. Defendant Secant Medical is a corporation located in Perkasie, Pennsylvania, which at all times material to this matter did business as a division, subsidiary, agent, representative of, and/or successor in interest to, and/or jointly with Defendants Secant Medical, Inc., Secant, Medical, LLC and/or Prodesco, Inc.

II. JURISDICTION AND VENUE

10. Plaintiff incorporates by reference all of the above paragraphs.

11. Jurisdiction and venue are proper in this Honorable Court, as Defendants all have sufficient contacts with the Commonwealth of Pennsylvania, including the City of Philadelphia, through their substantial and purposeful transaction of business there, including but not limited to their receipt of substantial compensation, revenues and/or profits from sales of the subject medical devices, synthetic mesh systems.

III. DEFENDANTS' PELVIC MESH PRODUCTS

12. In or about 2005, the J&J Defendants began to market and sell a product known as Prolift for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolift is medical device and a mesh woven from filaments of polypropylene and/or other non-biological substances that is designed and intended to be permanently implanted through surgery into the human body. (All references to Prolift include all variations of or names used for Prolift, including but not limited to UltraPro, Prolene, Gynemesh PS, Prolift +M, and Prosima.)

13. Prolift was derived from a product known as Prolene Mesh. Prolene Mesh was derived from the J&J Defendants' prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. (Prolene Mesh, UltraPro, Prolift, Prolift+M, and Gynemesh PS, as well as any unnamed pelvic mesh products designed and sold by the J&J Defendants for similar purposes, as well as the instruments and procedures sold by them for implantation of those products, are collectively referenced as the, "J&J Defendants' Pelvic Mesh Products and/or their Mesh Components.")

14. At all times relevant to this matter, the Secant Medical Defendants and/or the J&J Defendants designed, tested, inspected, wove, cut, treated, packaged, manufactured, marketed and/or sold a mesh made from polypropylene and/or other synthetically derived filaments that was the principal, active component of Defendant Johnson & Johnson's Mesh Products, including but not limited to Prolift. (Collectively, the mesh components of Defendants' Pelvic Mesh Products are referenced as the, "Mesh Components.")

15. The Pelvic Mesh Products and/or their Mesh Components were, manufactured, labeled, marketed, sold and distributed by the Defendants, at all times relevant herein.

16. The Defendants did so knowing and intending that the Pelvic Mesh Products and/or their Mesh Components would be implanted, surgically into women.

IV. FACTUAL BACKGROUND

17. On or about May 5, 2009, Plaintiff Patricia L. Hammons was implanted with one or more of the Defendant Johnson & Johnson's Pelvic Mesh Products and/or its Mesh Components, a surgical pelvic floor repair mesh packaged as Prolift, during a surgical procedure conducted upon by her surgeon.

18. The Secant Medical Defendants manufactured and sold the Mesh Components of the J&J Pelvic Mesh Products.

19. The Defendants' Pelvic Mesh Products and/or their Mesh Components were implanted in the Plaintiff to treat her stress pelvic floor prolapse, the uses for which the J&J Defendants and the Secant Medical Defendants manufactured, marketed, and/or sold them.

20. As a result of having the Pelvic Mesh Products and/or their Mesh Components implanted in her, Plaintiff Patricia L. Hammons has sustained permanent injury, and has experienced, and will continue to experience, significant mental and physical pain and suffering, financial or economic loss, including, but not limited to, obligations for medical services and expenses.

21. At all times relevant to this matter, the Defendants have marketed their Pelvic Mesh Products and/or their Mesh Components to the medical community and/or the medical device manufacturers and to patients and consumers as safe, effective, reliable, medical

devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence; and as safer and more effective as compared to the traditional products and procedures for treatment and other competing pelvic mesh products.

22. The Defendants have marketed and sold their Pelvic Mesh Products and/or their Mesh Components to medical device manufacturers, the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or include the provision of valuable consideration and benefits to health care providers. The Defendants also utilized documents, brochures, websites, and/or telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the products.

23. Contrary to the J&J Defendants' representations and marketing to the medical community and to the patients themselves, their Pelvic Mesh Products and/or their Mesh Components have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Patricia L. Hammons. In a study published based on a multi-center randomized controlled trial in August, 2010 in the Journal of the American College of Obstetricians and Gynecologists, it was concluded that there is a high (15.6%) vaginal mesh erosion (exposure of the mesh outside of the surgery site) rate with the Prolift, one of the Pelvic Mesh Products, "with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs."

24. The J&J Defendants in particular have consistently underreported and withheld information about the propensity of the their Pelvic Mesh Products and/or their Mesh Components to fail and to cause injury and complications, and have misrepresented the efficacy and safety of their Pelvic Mesh Products and/or their Mesh Components, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

25. The J&J Defendants have known, continue to know and at all times had reason to know that their disclosures to the FDA were and are incomplete and misleading; and that their Pelvic Mesh Products and/or their Mesh Components were and are causing numerous patients severe injuries and complications like those suffered by Plaintiff Patricia L. Hammons. The J&J Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the J&J Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that their Pelvic Mesh Products and/or their Mesh Components were and are safe and effective, leading to the prescribing and implantation of the Pelvic Mesh Products and/or their Mesh Components into the Plaintiff.

26. The J&J Defendants and/or the Secant Medical Defendants, individually and/or jointly failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products and/or their Mesh Components.

27. Knowing the significant risk that the Pelvic Mesh Products and/or their Mesh Components would fail and/or imperil the health and welfare of the women in which they

were implanted, Defendants failed to design the Pelvic Mesh Products and/or their Mesh Components for, and to establish a safe, effective procedure for, the removal of the Pelvic Mesh Products and/or their Mesh Components, rendering it impossible to safely or easily remove the Pelvic Mesh Products and/or their Mesh Components.

28. Feasible and suitable alternative designs and products, as compared to the Defendants' Pelvic Mesh Products and/or their Mesh Components, as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and other similar conditions, have existed at all times relevant.

29. The Pelvic Mesh Products and/or their Mesh Components were at all times utilized and implanted in a manner foreseeable to the Defendants.

30. The J&J Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products and/or their Mesh Components, and thus increase the sales of the Pelvic Mesh Product and/or its Mesh Components, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff Patricia L. Hammons.

31. The Pelvic Mesh Products and/or their Mesh Components implanted into Plaintiff Patricia L. Hammons were in the same or substantially similar condition as it was when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

32. The injuries, conditions, and complications suffered by Plaintiff Patricia L. Hammons due to the Pelvic Mesh Products and/or their Mesh Components include but are not limited to mesh erosion, mesh exposure, mesh contraction, infection, inflammation, scar tissue,

organ perforation, dyspareunia, blood loss, pelvic floor damage, pelvic pain, and recurrent urinary incontinence.

33. Despite knowledge of these catastrophic injuries, conditions, and complications caused by the Pelvic Mesh Products and/or their Mesh Components, the J&J Defendants had manufactured, marketed, and sold the Pelvic Mesh Products and/or their Mesh Components and the Secant Medical Defendants manufactured, prepared and sold their Mesh Components, while failing to adequately warn, label, instruct, and disseminate information with regard to the Pelvic Mesh Products and/or their Mesh Components, both prior to and after the marketing and sale of the Pelvic Mesh Product and/or its Mesh Components.

34. On or about January 3, 2012, the FDA ordered the Defendants to conduct randomized, controlled clinical testing of the Pelvic Mesh Products and/or their Mesh Components or be ordered to cease their manufacture, marketing and sale.

35. On or about June 5, 2012, the J&J Defendants announced that they were withdrawing some or all of the Pelvic Mesh Products and/or their Mesh Components from the market and, as a result, would not be conducting the randomized, controlled clinical testing ordered by the FDA.

36. As of the date of the filing of this Complaint, neither the J&J Defendants nor the Secant Defendants have ever begun or completed any of the randomized, controlled clinical testing ordered by the FDA.

COUNT I
STRICT LIABILITY DEFECTIVE MANUFACTURE AND DESIGN
PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

37. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

38. The Pelvic Mesh Products and/or their Mesh Components and their mesh components were defectively and improperly manufactured, rendering them deficient and unreasonably dangerous and hazardous to Plaintiff Patricia L. Hammons.

39. The Pelvic Mesh Products and/or their Mesh Components and their mesh components are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

40. The Pelvic Mesh Products and/or their Mesh Components and their mesh components create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products and/or their Mesh Components and their mesh components.

41. Defendants have intentionally and recklessly designed, manufactured, marketed, labeled, sold, and/or distributed the Pelvic Mesh Products and/or their Mesh Components with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiff Patricia L. Hammons and others.

42. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and/or distribution of the Pelvic Mesh Products and/or their Mesh Components, Plaintiff Patricia L. Hammons has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II
STRICT LIABILITY – FAILURE TO WARN
PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

43. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

44. The Defendants failed to properly and adequately warn and instruct the Plaintiff Patricia L. Hammons and her health care providers as to the proper candidates for, and the safest and most effective methods of implantation and use of, the Pelvic Mesh Products and/or their Mesh Components.

45. The Defendants failed to properly and adequately warn and instruct the Plaintiff Patricia L. Hammons and her health care providers as to the risks and benefits of the Pelvic Mesh Products and/or their Mesh Components, given Plaintiff Patricia L. Hammons 's conditions and need for information.

46. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products and/or their Mesh Components, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products and/or their Mesh Components.

47. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Pelvic Mesh Products and/or their Mesh Components, understating the risks and exaggerating the benefits in order to advance their own financial

interests, with wanton and willful disregard for the rights and health of the Plaintiff Patricia L. Hammons

48. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the Pelvic Mesh Products and/or their Mesh Components, Plaintiff Patricia L. Hammons has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT III
NEGLIGENCE
PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

49. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

50. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Pelvic Mesh Products and/or their Mesh Components.

51. Defendants breached their duty of care to the Plaintiff Patricia L. Hammons, in the manufacture, design, labeling, warnings, instructions, sale, marketing, and distribution of the Pelvic Mesh Products and/or their Mesh Components.

52. The J&J Defendants had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians and surgeons to implant the Pelvic Mesh Products and/or their Mesh Components.

53. The J&J Defendants breached their duty of care to Plaintiff Patricia L. Hammons in the recruitment and training of physicians and surgeons to implant the Pelvic Mesh Products and/or their Mesh Components.

54. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products and/or their Mesh Components and/or of the J&J Defendants' recruitment and training of physicians and surgeons to implant the Pelvic Mesh Products and/or their Mesh Components, Plaintiff Patricia L. Hammons has been injured catastrophically and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum, in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV
COMMON LAW FRAUD
PAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

55. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

56. The Defendants falsely and fraudulently have represented and continue to represent to medical device manufacturers, the medical and healthcare community, Plaintiff Patricia L. Hammons, the FDA, and/or the public that the Pelvic Mesh Products and/or their Mesh Components had been appropriately tested and were found to be safe and effective.

57. The representations made by the Defendants were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those

representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products and/or their Mesh Component.

58. These representations were made by the Defendants with the intent of defrauding and deceiving medical device manufacturers, the medical community, Plaintiffs, and the public, and also inducing the medical community, Plaintiff Patricia L. Hammons, and/or the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products and/or their Mesh Components for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff Patricia L. Hammons.

59. In representations to Plaintiff Patricia L. Hammons and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted the following material information:

- a) That the Pelvic Mesh Products and/or their Mesh Components were not as safe as other products and procedures available to treat incontinence and/or prolapse;
- b) That the risk of adverse events with the Pelvic Mesh Products and/or their Mesh Components was higher than with other products and procedures available to treat incontinence and/or prolapse;
- c) The Pelvic Mesh Products and/or their Mesh Components were not adequately tested;
- d) That the limited clinical testing revealed the Pelvic Mesh Products and/or their Mesh Components had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;
- e) That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from

physicians and other healthcare providers and buried and/or misrepresented those findings;

- f) That Defendants were aware of dangers in the Pelvic Mesh Products and/or their Mesh Components in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;
- g) That the Pelvic Mesh Products and/or their Mesh Components were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;
- h) That patients needed to be monitored more regularly than usual while implanted with the Pelvic Mesh Products and/or their Mesh Components and, if the products needed to be removed, that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;
- i) That the Pelvic Mesh Products and/or their Mesh Components were manufactured negligently;
- j) That the Pelvic Mesh Products and/or their Mesh Components were manufactured defectively; and
- k) That the Pelvic Mesh Products and/or their Mesh Components were designed negligently and designed defectively.

60. The Defendants were under a duty to disclose to Plaintiff Patricia L. Hammons and her physicians and surgeons, the defective nature of the Pelvic Mesh Products and/or their Mesh Components, including, but not limited to, the heightened risks of erosion, exposure, failure and permanent injury.

61. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Pelvic Mesh Products and/or their Mesh Components.

62. The Defendants' concealment and omissions of material facts concerning the safety of the Pelvic Mesh Products and/or their Mesh Components were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff Patricia L. Hammons, Plaintiff Patricia L. Hammons's physicians, surgeons and healthcare providers and induce them to purchase, prescribe, and/or dispense the Pelvic Mesh Product and/or its Mesh Components; and/or to mislead them into reliance upon and cause them to use the Pelvic Mesh Products and/or their Mesh Components.

63. At the time these representations were made by the Defendants, and at the time Plaintiff Patricia L. Hammons and/or her healthcare providers, used the Pelvic Mesh Product and/or its Mesh Component s, Plaintiff Patricia L. Hammons and/or her healthcare providers were unaware of the falsehood of these representations, and reasonably believed them to be true.

64. The Defendants knew and had reason to know that the Pelvic Mesh Products and/or their Mesh Components could and would cause severe and grievous personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

65. In reliance upon these false representations, Plaintiff Patricia L. Hammons was induced to, and did use the Pelvic Mesh Products and/or their Mesh Components, thereby sustaining severe and permanent personal injuries and damages. The Defendants knew or had reason to know that Plaintiffs and their physicians and other healthcare providers had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Pelvic Mesh Products and/or their Mesh Components, as described in detail herein.

66. Plaintiff Patricia L. Hammons reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Pelvic Mesh Products and/or their Mesh Components.

67. Having knowledge based upon the J&J Defendants' research and testing, or lack thereof, the J&J Defendants blatantly and intentionally distributed false information, including but not limited to assurances to Plaintiff Patricia L. Hammons, the public, and Plaintiff Patricia L. Hammons's healthcare providers and physicians, that the Pelvic Mesh Products and/or their Mesh Components were safe for use as a means of providing relief from stress urinary incontinence and/or pelvic organ prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Defendants' research and testing, or lack thereof, these Defendants intentionally omitted, concealed and suppressed the dissemination of certain results of testing and research to healthcare professionals, Plaintiff Patricia L. Hammons, and the public at large.

68. The Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, medical device manufacturers, Plaintiff Patricia L. Hammons, her healthcare providers, and the FDA.

69. The information distributed to the public, the medical community, the medical device manufacturers, the FDA, and Plaintiff Patricia L. Hammons by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material

representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of the Pelvic Mesh Products and/or their Mesh Components.

70. These representations, and others made by the Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

71. The Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products and/or their Mesh Components to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

72. At the time the representations were made, Plaintiff Patricia L. Hammons and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Pelvic Mesh Products and/or their Mesh Components.

73. Plaintiff Patricia L. Hammons did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff Patricia L. Hammons discover the false representations of the J&J Defendants, nor would Plaintiff Patricia L. Hammons with reasonable diligence have discovered the true facts about the J&J Defendant's misrepresentations at the time when the Pelvic Mesh Product and/or its Mesh Component was implanted surgically into her.

74. Had Plaintiff Patricia L. Hammons known the true facts about the dangers and serious health and/or safety risks of the Pelvic Mesh Products and/or their Mesh Components, Plaintiff Patricia L. Hammons would not have purchased, used, or relied on Defendants' representations and omissions concerning the Pelvic Mesh Products and/or their Mesh Components.

75. The Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff Patricia L. Hammons.

76. As a proximate result of the Defendants' conduct Plaintiff Patricia L. Hammons has been injured catastrophically and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V
NEGLIGENT MISREPRESENTATION
PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

77. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

78. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical device manufacturers, Plaintiff Patricia L. Hammons, her healthcare providers and the public, that the Pelvic Mesh Products and/or their Mesh Components had been tested and found to be safe and effective for the treatment of stress urinary incontinence and pelvic organ prolapse.

79. Those representations made by the Defendants, in fact, were false.

80. The Defendants failed to exercise ordinary care in making their the representations concerning the Pelvic Mesh Products and/or their Mesh Components while they

were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because the Defendants negligently misrepresented the Pelvic Mesh Products and/or their Mesh Components' high risk of unreasonable and dangerous adverse side effects.

81. The Defendants breached their duty in representing that the Pelvic Mesh Products and/or their Mesh Components have no serious side effects different from older generations of similar products and/or procedures to Plaintiff Patricia L. Hammons, her physicians, and the medical and healthcare community.

82. As a foreseeable, direct and proximate result of the negligent misrepresentation of the Defendants as set forth herein, the Defendants knew, and had reason to know, that the Pelvic Mesh Products and/or their Mesh Components had been insufficiently tested, or had not been tested at all, that the products lacked adequate and accurate warnings, that they created a high risk, and/or higher than acceptable risk, and/or higher than reported risk and that they represented a risk of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

83. As a proximate result of the Defendants' conduct, Plaintiff Patricia L. Hammons has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for

costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VI
NEGLIGENT INFLECTION OF EMOTIONAL DISTRESS

PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

84. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

85. The Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Pelvic Mesh Products and/or their Mesh Components to Plaintiff Patricia L. Hammons, carelessly and negligently concealing the harmful effects of the Pelvic Mesh Products and/or their Mesh Components from Plaintiffs, and carelessly and negligently misrepresenting the quality, safety and efficacy of the products.

86. Plaintiff Patricia L. Hammons was directly impacted by the Defendants' carelessness and negligence, in that she has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Pelvic Mesh Products and/or their Mesh Components sold and distributed by the Defendants.

87. As a proximate result of the Defendants' conduct, Plaintiff Patricia L. Hammons has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII
BREACH OF EXPRESS WARRANTY

PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

88. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

89. At all relevant and material times, the Defendants manufactured, distributed, advertised, promoted, and sold the Pelvic Mesh Products and/or their Mesh Components.

90. At all relevant times, the Defendants intended that the Pelvic Mesh Products and/or their Mesh Components be used in the manner that Plaintiff Patricia L. Hammons used them and they expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for pelvic organ prolapse and/or stress urinary incontinence, and that they were adequately tested and fit for their intended use.

91. At all relevant times, the Defendants were aware that consumers, including Plaintiff Patricia L. Hammons, would use the Pelvic Mesh Product; which is to say that Plaintiff Patricia L. Hammons was a foreseeable user of the Pelvic Mesh Products and/or their Mesh Components.

92. Plaintiff Patricia L. Hammons and/ or her implanting physicians were at all relevant times in privity with the Defendants.

93. The Pelvic Mesh Products and/or their Mesh Components were expected to reach and did in fact reach its ultimate consumer, including Plaintiff Patricia L. Hammons and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by the Defendants.

94. The Defendants breached various express warranties with respect to the Pelvic Mesh Product including the following particulars:

- a) The Defendants represented to Plaintiff Patricia and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Pelvic Mesh Products and their Mesh Components were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products and/or their Mesh Components;
- b) The Defendants represented to Plaintiff Patricia L. Hammons and her physicians and healthcare providers that the Pelvic Mesh Products and/or their Mesh Components were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Pelvic Mesh Products and/or their Mesh Components were not safer than alternatives available on the market; and
- c) The Defendants represented to Plaintiff Patricia L. Hammons and her physicians and healthcare providers that the Pelvic Mesh Products and/or their Mesh Components were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

95. In reliance upon the Defendants' express warranties, Plaintiff Patricia L. Hammons was implanted with the Pelvic Mesh Products and/or their Mesh Components as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

96. At the time of making such express warranties, the Defendants knew or should have known that the Pelvic Mesh Products and/or their Mesh Components do not conform to these express representations because the Pelvic Mesh Products and/or their Mesh Components were not safe and had numerous serious side effects, many of which the Defendants did not accurately warn about, thus making the Pelvic Mesh Products and/or their Mesh Components unreasonably unsafe for their intended purpose.

97. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff Patricia L. Hammons, relied upon the representations and warranties of the Defendants in connection with the use, recommendation, description, and/or dispensing of the Pelvic Mesh Products and/or their Mesh Components.

98. The Defendants breached their express warranties to Plaintiff Patricia L. Hammons in that the Pelvic Mesh Products and/or their Mesh Component were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

99. The Defendants' breaches constituted violations of common law principles and 13 Pa. Stat. Ann. § 2313, *et seq.*

100. As a proximate result of the Defendants' conduct, Plaintiff Patricia L. Hammons has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII
BREACH OF IMPLIED WARRANTY
PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

101. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

102. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Pelvic Mesh Products and/or their Mesh Components.

103. At all relevant times, Defendants intended that the Pelvic Mesh Products and/or their Mesh Components to be implanted for the purposes and in the manner that Plaintiff Patricia L. Hammons or her physicians or surgeons used them and the Defendants impliedly warranted each Pelvic Mesh Product and/or its Mesh Component to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

104. Defendants were aware that consumers, including Plaintiff Patricia L. Hammons or her physicians and surgeons would implant the Pelvic Mesh Product and/or its Mesh Component in the manner directed by the instructions for use and that Plaintiff Patricia L. Hammons was the foreseeable user of the Pelvic Mesh Products and/or their Mesh Components.

105. Plaintiff Patricia L. Hammons and/or her physicians and surgeons were at all relevant times in privity with Defendants.

106. The Defendants' Pelvic Mesh Products and/or their Mesh Components were expected to reach and did in fact reach consumers, including Plaintiff Patricia L. Hammons and/or her physicians and surgeons, without substantial change in the condition in which they manufactured and sold by Defendants.

107. Defendants breached various implied warranties with respect to the Pelvic Mesh Products and/or their Mesh Components, including the following particulars:

- a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, medical literature, and regulatory submissions that the Pelvic Mesh Products and/or their Mesh Components were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products and/or their Mesh Components ;
- b) Defendants represented that the Pelvic Mesh Products and/or their Mesh Components were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Pelvic Mesh Products and/or their Mesh Components were not as safe or safer than alternatives available on the market; and
- c) Defendants represented that the Pelvic Mesh Products and/or their Mesh Components were more efficacious than other alternative treatments and fraudulently concealed information, regarding the true efficacy of the Pelvic Mesh Products and/or their Mesh Components.

108. In reliance upon Defendants' implied warranties, Plaintiff Patricia L. Hammons and/or her implanting physicians and surgeons used the Pelvic Mesh Products and/or their Mesh Components as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

109. Defendants breached their implied warranties to Plaintiff Patricia L. Hammons and/or her implanting physicians and surgeons in that the Pelvic Mesh Products and/or their Mesh Components were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of common law principles and the following statutory provisions: N.J. Stat. Ann. §§ 12A:2-314, *et seq.* and 13 Pa. Stat. Ann. §§ 2314 *et seq.*

110. As a proximate result of the Defendants' conduct, Plaintiff Patricia L. Hammons has been injured catastrophically, and sustained severe and permanent pain, suffering,

disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IX
VIOLATION OF CONSUMER PROTECTION LAW

PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

111. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

112. Plaintiff Patricia L. Hammons purchased and used the Pelvic Mesh Product and/or its Mesh Component primarily for personal use and thereby suffered ascertainable losses as a result of the Defendants' actions in violation of the consumer protection laws.

113. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff Patricia L. Hammons would not have purchased and/or paid for the Defendants' Pelvic Mesh Products and/or their Mesh Components, and would not have incurred related medical costs and injury.

114. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff Patricia L. Hammons for the Pelvic Mesh Products and/or their Mesh Components, that were implanted into her, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

115. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;
- b) Advertising goods or services with the intent not to sell them as advertised; and,
- c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

116. Plaintiff Patricia L. Hammons was injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, physicians and consumers, including Plaintiff Patricia L. Hammons, was to create demand for and sell the Pelvic Mesh Products and/or their Mesh Components. Each aspect of the Defendants' conduct combined to artificially create sales of the Pelvic Mesh Products and/or their Mesh Components.

117. The Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Pelvic Mesh Products and/or their Mesh Components.

118. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff Patricia L. Hammons would not have purchased and/or paid for the Pelvic Mesh Product and/or its Mesh Components, and would not have incurred related medical costs.

119. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff Patricia L. Hammons, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes, including but not limited to 73 Pa. Stat. §§ 201-1 *et seq.*

120. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, including but not limited to of 73 Pa. Stat. §§ 201-1 *et seq.*

121. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

122. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Pelvic Mesh Products and/or their Mesh Components were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

123. The actions and omissions of the Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

124. The Defendants had actual knowledge of the defective and dangerous condition of the Pelvic Mesh Products and/or their Mesh Components and failed to take any action to cure such defective and dangerous conditions.

125. Plaintiff Patricia L. Hammons and her implanting physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform.

126. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

127. By reason of the unlawful acts engaged in by the Defendants, and as a direct and proximate result thereof, Plaintiff Patricia L. Hammons has suffered ascertainable losses and damages.

128. As a direct and proximate result of the Defendants' violations of the state's consumer protection laws, Plaintiff Patricia L. Hammons has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT X
GROSS NEGLIGENCE

PLAINTIFF PATRICIA L. HAMMONS v. ALL DEFENDANTS

129. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

130. The wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff

Patricia L. Hammons , for which the law would allow, and which Plaintiff Patricia L. Hammons will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff Patricia L. Hammons; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representations that were false, with Defendants, knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff Patricia L. Hammons.

131. Plaintiff Patricia L. Hammons relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

132. Plaintiff Patricia L. Hammons therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

133. Plaintiff Patricia L. Hammons also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff Patricia L. Hammons. In that regard, Plaintiff Patricia L. Hammons will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future

WHEREFORE, Plaintiff Patricia L. Hammons demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

Respectfully submitted,

KLINE & SPECTER
A Professional Corporation



Thomas R. Kline, Esquire/28895

Lee B. Balefsky, Esquire/25321

Michelle L. Tiger, Esquire/43872

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Philadelphia, PA 19102

(215) 772-1000

Attorneys for Plaintiff
Patricia L. Hammons

VERIFICATION

I, PATRICIA HAMMONS, being duly sworn according to law, depose and state:

1. I am the plaintiff in this action;
2. I verify that the statements made in the foregoing Complaint are true and correct to the best of our knowledge or information and belief; and
3. I understand that the statements made in said Complaint are subject to the penalties of 18 Pa.C.S. Section 4904 relating to unsworn falsification to authorities.


PATRICIA HAMMONS

DATED: _____